



Pfizer Global Regulatory Affairs  
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## Global Product Development

3 May 2021

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**Re: Emergency Use Authorization (EUA) 27034**

**Pfizer-BioNTech COVID-19 Vaccine**

**Response to FDA 30 April 2021 Information Request**

Dear Dr. Gruber,

Reference is made to the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine for the active immunization to prevent COVID-19 in individuals  $\geq 16$  years of age and older issued on 11 December 2020. Further reference is made to the Amendment to the EUA submitted 09 April 2021 to extend the indication to 12 years of age.

Reference is also made to comments on the draft Healthcare Provider Factsheet/Full EUA Prescribing Information received from the Agency on 30 April 2021.

The following updated documents for the Healthcare Provider Factsheet/Full EUA Prescribing Information are provided in Module 1.14.1:

- Track change ([Word](#))
- Annotated ([PDF](#))
- Clean copy ([PDF](#) and [Word](#))

CBER confirmed via email on 30 April 2021 that they have accepted Pfizer's proposed revisions to the Recipient and Caregiver Fact Sheet as proposed on 09 April 2021 therefore no updated documents are needed for this document.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 212-733-2613; via facsimile at 845-474-3500; or via e-mail at [neda.aghajanimemar@pfizer.com](mailto:neda.aghajanimemar@pfizer.com).

Sincerely,

Neda Aghajani Memar, Pharm.D.  
Director  
Pfizer Global Regulatory Affairs

CC: Ramachandra S. Naik, Ph.D.  
CC: Laura Gottschalk, Ph.D.